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| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|--------------------|------------|----------------------|-------------------------|------------------|
| 09/929,590 | 08/14/2001 | | John R. Reynolds | 41530/28295 | 3647 |
| 21888 | 7590 | 01/15/2004 | | EXAMINER | |
| THOMPSO | | • | DESANTO, MATTHEW F | | |
| ONE US BANK PLAZA SUITE 3500 | | | ART UNIT | PAPER NUMBER | |
| | ST LOUIS, MO 63101 | | | 3763 | 12 |
| | | | | DATE MAILED: 01/15/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|--|---|--|--|--|--|--|--|
| | 09/929,590 | REYNOLDS ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Matthew F DeSanto | 3763 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 66(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | | |
| 1) Responsive to communication(s) filed on 17 Oc | ctober 2003. | | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ This a | action is non-final. | | | | | | |
| 3) Since this application is in condition for allowar closed in accordance with the practice under E | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) Claim(s) 54-63 is/are pending in the application 4a) Of the above claim(s) is/are withdrav 5) Claim(s) is/are allowed. 6) Claim(s) 54-63 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or | vn from consideration. | | | | | | |
| Application Papers | · | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | | Examiner. | | | | | |
| Applicant may not request that any objection to the o | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correcti | on is required if the drawing(s) is obj | jected to. See 37 CFR 1.121(d). | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. a) The translation of the foreign language provisional application has been received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) ☑ Notice of References Cited (PTO-892) 2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal P | (PTO-413) Paper No(s) latent Application (PTO-152) | | | | | |

Page 2

Application/Control Number: 09/929,590

Art Unit: 3763

DETAILED ACTION

Claim Objections

1. The Claim objection is withdrawn because of amendments to the claim.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 54-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Gresser et al. (USPN 5,429,822).

Gresser et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually. (Fig. 1-3 and entire reference)

4. Claims 54-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Pickett et al. (USPN 6,132,752).

Application/Control Number: 09/929,590 Page 3

Art Unit: 3763

5. Pickett et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually. (Fig. 1A and entire reference)

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 54-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (USPN 4585652).

Miller et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually (Fig. 1, 2 and entire reference, Column 2, lines 50-68, Column 6, lines 59-65)

Application/Control Number: 09/929,590 Page 4

Art Unit: 3763

At the time of the invention it would have been obvious for one of ordinary skill in to modify Miller et al. to have two electrodes because it is well known that duplicating the components of a prior art device is a design consideration within the skill of the art.

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), and therefore, a mere modification that would have been obvious.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-8, 14-24, 44-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 09/929197. Although the conflicting claims are not identical, they are not patentably distinct from each other because having an electroactive polymer and the use of burst electrodes.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application/Control Number: 09/929,590 Page 5

Art Unit: 3763

Response to Arguments

10. Applicant's arguments with respect to claims 54-63 have been considered but are most in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

SUPUTIONS OF PATENT EXAMINER TECHNOLOGY CENTER SOOO

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

Matthew DeSanto Art Unit 3763

January 12, 2004